# CHAPTER 9.5.

# <u>INFECTION WITH HEPATOBACTER PENAEI</u> <u>(NECROTISING HEPATOPANCREATITIS)</u>

Article 9.5.1.

For the purposes of the *Aquatic Code*, <u>infection with *Hepatobacter penaei*</u> necrotising hepatopancreatitis (NHP) means infection with Candidatus *Hepatobacter penaei*. This <u>an</u> obligate intracellular bacterium is a member of the erder Order α-Proteobacteria. The disease is commonly known as necrotising hepatopancreatitis.

Article 9.5.2.

## Scope

The recommendations in this chapter apply to the following susceptible species which meet the criteria for listing species as susceptible in Chapter 1.5.: Pacific white white leg shrimp (Penaeus vannamei), blue shrimp (P. stylirostris), northern white shrimp (P. setiferus) and northern brown shrimp (P. aztecus). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose regardless of the infection with *H. penaei* status of the exporting country, zone or compartment from a country, zone or compartment not declared free from necrotising hepatopancreatitis

- 1) Competent Authorities should not require any conditions related to <u>infection with H. penaei</u> NHP, regardless of the <u>infection with H. penaei</u> NHP status of the exporting country, zone or compartment, when authorising the importation or transit of the following aquatic animal products from the species referred to in Article 9.5.2. which are intended for any purpose and which comply with Article 5.4.1.:
  - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
  - b) cooked crustacean products that have been subjected to heat treatment at 100°C for at least three minutes (or any time/temperature equivalent which has been demonstrated to inactivate Candidatus H. penaei);
  - c) pasteurised crustacean products that have been subjected to heat treatment at 63°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate Candidatus H. penaei);
  - d) crustacean oil;
  - e) crustacean meal;
  - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.5.2., other than those referred to in point 1 of Article 9.5.3., *Competent Authorities* should require the conditions prescribed in Articles 9.5.7. to 9.5.11. relevant to the <u>infection with *H. penaei*</u> NHP status of the exporting country, zone or compartment.

When considering the importation or transit of aquatic animals and aquatic animal products of a species not covered in Article 9.5.2. but which could reasonably be expected to pose a risk of spread of infection with H. penaei NHP, the Competent Authority should conduct a risk analysis in accordance with the recommendations in Chapter 2.1. The Competent Authority of the exporting country should be informed of the outcome of this assessment.

Article 9.5.4.

## Country free from infection with H. penaei necrotising hepatopancreatitis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from <u>infection with *H. penaei*</u> NHP if all the areas covered by the shared water bodies are declared countries or *zones* free from infection with *H. penaei* NHP (see Article 9.5.5.).

As described in Article 1.4.6., a country may make a self-declaration of freedom from infection with H. penaei NHP if:

 none of the susceptible species referred to in Article 9.5.2. are present and basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 2) any of the susceptible species referred to in Article 9.5.2. are present and the following conditions have been met:
  - a) there has been no observed occurrence of the disease for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the Aquatic Manual);
     and
  - b) basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 3) the disease status prior to targeted surveillance is unknown but the following conditions have been met:
  - a) basic biosecurity conditions have been continuously met for at least the last two years; and
  - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with *H. penaei* NHP;

OR

- 4) it previously made a self-declaration of freedom from <u>infection with H. penaei</u> NHP and subsequently lost its disease free status due to the detection of <u>infection with H. penaei</u> NHP but the following conditions have been met:
  - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* likelihood of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in Chapter 4.3.) have been completed; and
  - previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place since eradication of the disease; and
  - d) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with *H. penaei* NHP.

In the meantime, part or all of the non-affected area may be declared a free zone provided that such a part meets the conditions in point 3 of Article 9.5.5.

Article 9.5.5.

#### Zone or compartment free from infection with H. penaei necrotising hepatopancreatitis

If a zone or compartment extends over more than one country, it can only be declared <u>a</u> an NHP free zone or compartment free from infection with <u>H. penaei</u> NHP if all the relevant Competent Authorities confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from <u>infection with *H. penaei*</u> NHP may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

 none of the susceptible species referred to in Article 9.5.2. are present in the zone or compartment and basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.5.2. are present in the *zone* or *compartment* and the following conditions have been met:
  - there has not been any observed occurrence of the disease for at least the last ten years despite
    conditions that are conducive to its clinical expression (as described in the corresponding chapter of the
    Aquatic Manual); and
  - b) basic biosecurity conditions have been continuously met for at least the last two years;

OR

- 3) the disease status prior to targeted surveillance is unknown but the following conditions have been met:
  - a) basic biosecurity conditions have been continuously met for at least the last two years; and
  - b) targeted surveillance, as described in Chapter 1.4., has been in place, in the zone or compartment, for at least the last two years without detection of <u>infection with H. penaei</u> NHP;

OR

- 4) it previously made a *self-declaration of freedom* in the *zone* from <u>infection with *H. penaei* NHP</u> and subsequently lost its *disease* free status due to the detection of <u>infection with *H. penaei* NHP</u> in the *zone* but the following conditions have been met:
  - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk <u>likelihood</u> of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in Chapter 4.3.) have been completed; and
  - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
  - d) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with *H. penaei* NHP.

#### Maintenance of free status

A country, *zone* or *compartment* that is declared free from <u>infection with *H. penaei*</u> NHP following the provisions of points 1 or 2 of Articles 9.5.4. or 9.5.5. (as relevant) may maintain its status as free from <u>infection with *H. penaei*</u> NHP provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from <u>infection with *H. penaei*</u> NHP following the provisions of point 3 of Articles 9.5.4. or 9.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from <u>infection with *H. penaei*</u> NHP provided that conditions that are conducive to clinical expression of <u>infection with <u>H. penaei</u> NHP, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.</u>

However, for declared free zones or compartments in infected countries and in all cases where conditions are not conducive to clinical expression of infection with H. penaei NHP, targeted surveillance needs to be continued at a level determined by the Aquatic Animal Health Service on the basis of the likelihood of infection.

Article 9.5.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from <u>infection with H. penaei</u> necrotising hepatopancreatitis

When importing aquatic animals and aquatic animal products of species referred to in Article 9.5.2. from a country, zone or compartment declared free from infection with <u>H. penaei</u> NHP, the Competent Authority of the importing country should require that the consignment be accompanied by an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 9.5.4. or 9.5.5. (as applicable) and 9.5.6., the place of production of the aquatic animals and aquatic animal products is a country, zone or compartment declared free from infection with <u>H. penaei</u> NHP.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.5.3.

Article 9.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from  $\underline{infection \ with \ \textit{H. penaei}}$   $\underline{necrotising}$   $\underline{hepatopancreatitis}$ 

- 1) When importing, for aquaculture, live aquatic animals of species referred to in Article 9.5.2. from a country, zone or compartment not declared free from <u>infection with H. penaei</u> NHP, the Competent Authority of the importing country should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
  - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
  - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of Candidatus H. *penaei*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx) may be summarised to the following points:

- a) identify stock of interest (cultured or wild) in its current location;
- b) evaluate stock health and disease history;
- c) take and test samples for Candidatus H. penaei, pests and general health/disease status;
- d) import of a founder (F-0) population and quarantine in a secure facility;
- e) produce F-1 generation from the F-0 stock in *quarantine*:
- f) culture F-1 stock and at critical times in its development (life cycle) sample and test for Candidatus *H. penaei* and perform general examinations for pests and general health/disease status;
- g) if Candidatus *H. penaei* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as <u>free from infection with *H. penaei*</u> NHP free or specific pathogen free (SPF) for Candidatus *H. penaei*;
- h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- With respect to point 3 e), quarantine conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If quarantine conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low infection level.

This Article does not apply to aquatic animals listed in point 1 of Article 9.5.3.

Article 9.5.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from  $\underline{\text{infection with}}$  H. penaei  $\underline{\text{necrotising hepatopancreatitis}}$ 

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from <u>infection with *H. penaei*</u> NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one
  of the products referred to in point 1 of Article 9.5.3., or products described in point 1 of Article 9.5.11., or other
  products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of Candidatus H. or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.5.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from  $\underline{\text{infection with $H$. penaei}}$   $\underline{\text{necrotising hepatopancreatitis}}$ 

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from <u>infection with *H.* penaei NHP</u>, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and

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2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of Candidatus *H. penaei*.

This Article does not apply to commodities referred to in point 1 of Article 9.5.3.

Article 9.5.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from  $\underline{infection\ with\ }$   $\underline{H.\ penaei}$   $\underline{necrotising\ hepatopancreatitis}$ 

1) Competent Authorities should not require any conditions related to <u>infection with H. penaei</u> NHP, regardless of the <u>infection with H. penaei</u> NHP status of the <u>exporting country</u>, zone or <u>compartment</u>, when authorising the importation or transit of frozen peeled shrimp (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2) When importing aquatic animals or aquatic animal products, other than those referred to in point 1 above, of species referred to in Article 9.5.2. from a country, zone or compartment not declared free from infection with H. penaei NHP, the Competent Authority of the importing country should assess the risk and apply appropriate risk mitigation measures.